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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,384	08/19/2003	Kenneth Brasel	2836-H	4836

23373 7590 01/29/2008
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,384	BRASEL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 10/26/2007 has been entered.

Applicant's amendment, filed 10/26/2007, has been entered.

Claims 1-23 are pending.

Again, applicant's election of the species bacteria in the Response to Election of Species Requirement, filed 7/19/06, has been acknowledged.

As indicated previously, upon further consideration and search, the species has been extended to both bacterial and viral for examination purposes to advance prosecution.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 10/26/2007.

The rejections of record can be found in previous Office Actions, mailed 10/06/2006 and 05/03/2007.

It is noted that applicant's arguments and the examiner's rebuttal are essentially the same of record and will be addressed in the following Priority Section.

3. Priority.

Applicant's arguments including reliance upon In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977), filed 10/262008, have been fully considered but have not been found convincing with respect to the priority of the instant claims.

Again, applicant essentially relies upon that disclosure of the instant and the priority applications disclose the situation where the antigen, such as a bacterial or viral antigen, may already exist with the patient and that the Flt3-ligand may be administered as a vaccine adjuvant to enhance an immune response to the viral or bacterial antigens.

Applicant submits that that it is clear that the instant specification and the priority applications disclose treatment of infection *generally* as the presence of the bacterial or viral antigen in the patient would arise as a result of the patient being infected with the bacteria or virus

and submits that two species (e.g., "viral or bacterial antigens/infection") of the genus are described.

While, it is noted that "infection" is broad, that "viral and bacterial infections" are broad as well albeit "bacterial and viral infections" that can be considered species of the broader genus of "infection";

the current claims now rely upon "HIV" as a species that is yet another class/subgenus/species that is much smaller than either "infection or viral / bacterial infections" originally disclosed in the instant or priority applications.

"Infections", "viral/bacterial infections" and "HIV infection" differ in orders of magnitude.

With respect to applicant's reliance upon USSN 09/444,072 for support for the "proviso that the infectious disease is not HIV";

Again, it is noted that USSN 09/444,072 does not provide written support for "HIV" or "treating patients with an infection with HIV".

With respect to applicant's reliance upon U.S. Patent No. 5,554,512 for support for the "proviso that the infectious disease is not HIV" in USSN 08/725,540;

the following description concerning U.S. Patent No. 5,554,512 can be found in USSN 08/725,540.

As used herein, the term "flt3-ligand" refers to a genus of polypeptides that are described in U.S. Pat. No. 5,554,512, EP 0627487 A2 and in WO 94/28391, both incorporated herein by reference. A human flt3-ligand cDNA was deposited with the American Type Culture Collection, Rockville, Md., USA (ATCC) on Aug. 6, 1993 and assigned accession number ATCC 69382. The deposit was made under the terms of the Budapest Treaty. Flt3-L can be made according to the methods described in the documents cited above.

See pages 4-5, overlapping paragraph of USSN 08/725,540.

Applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents.

See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973).

Therefore, the priority application USSN 08/725,540 appears to only rely upon U.S. Patent No. 5,554,512 for a description of "flt3-ligand"
and not for the disclosure of treating patients having infectious diseases
and more particularly, not for the disclosure of treating patients having an HIV infection.

In contradistinction to applicant's reliance upon In re Johnson and Farnham,
applicant's reliance upon the instant and priority applications do not provide sufficient disclosure of a broad and complete disclosure coupled with with extensive examples fully supported of the limited genus encompassing the negative proviso no claimed.

Therefore, it is maintained that the negative proviso introduces a new subgenus, where the specification nor the priority documents provide a sufficient description of the species HIV itself.

In addition, it is maintained that the negative proviso introduces a new subgenus,
where the specification and the priority documents do not provide a sufficient number of species to establish entitlement to the claimed negative proviso.

The following is reiterated for applicant's convenience.

As acknowledged by applicant and indicated previously,
in contrast to the reliance upon viral and bacterial infections to support the genus of "infectious diseases",
an infectious disease is a clinically evident disease of humans or animals that damages or injures the host so as to impair host function, and results from the presence and activity of one or more pathogenic microbial agents, including viruses, bacteria, fungi, protozoa, multicellular parasites, and aberrant proteins known as prions.
Also, it is noted that an infection however, is not synonymous with an infectious disease, as an infection may not cause clinical symptoms or impair host function.

Again, the recitation of HIV is not readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

Again, while negative limitations as set forth in the newly submitted "provisio" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.

Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

Therefore, the examiner maintains that the filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.

For example, it appears that the only support for the written description of "methods of treating infection in a patient having an infection" is the original claims of the instant application and not the instant specification, nor in the priority documents relied upon.

While the priority documents and the instant specification do disclose "the antigen may be one that already exists within the patient, such as a tumor antigen, or a bacterial or viral antigen" (e.g. see Summary of the Invention) or "flt3-L may be administered as a vaccine adjuvant ... for immunization purposes to enhance an immune response against tumor, viral or bacterial antigens" (e.g., see page 14, paragraph 2 of the instant specification),

Neither the instant specification nor the previous priority documents provide a sufficient written description for the broader genus of "treating an infection", broadly encompassed by the instant claims.

For example the reliance upon bacterial and viral antigens existing in patients or vaccines does not support broadening the disclosure of the priority documents to "treating infections", broadly encompassed by the instant claims.
Also, see MPEP 2163.05.

Again, if applicant desires priority prior to 8/19/2003 for the instant claims,
applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Therefore, while applicant notes that the instant application is filed as a Divisional of pending USSN 10/241,927, which is a continuation of USSN 09/444,027;
it is maintained that this application repeats a substantial portion of prior USSN 10/241,927, filed 09/11/2002 and adds and claims additional disclosure not presented in the prior application, as indicated above.

Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

4. Applicant's arguments and the examiner's rebuttal concerning priority and sufficient written description of the claimed methods in the application (and, in turn, the specification) have been addressed above in the Section on priority.

As noted above, the claims now also recite "with the proviso that said infectious disease is not HIV".

Also, the recitation of HIV is not readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "provisio" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.

Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

Therefore, the examiner maintains that the filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l).
Correction of the following is required:

As indicated above with respect to priority and upon a review of the instant specification, it does not appear that the instant specification provides for antecedent basis for the recitation of "methods of treating infection in a patient having an infection" other than in the original claims of the instant application.

Again, this "limitation" including the newly submitted "proviso" is not readily apparent in the instant specification, nor in the priority documents relied upon.

Applicant should note the New Matter rejection set forth herein due to the submission of the "proviso".

Alternatively, applicant is invited to identify the written support for instant claims in the specification as filed (and as well as any USSN document relied upon for priority).

5. This is a rejection under 35 USC, 112, first paragraph, Written Description / New Matter.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.
The specification as originally filed does not provide support for the invention as now claimed: "with the proviso that said infectious disease is not HIV".

Applicant's amendment, filed 10/26/2007, does not appear to provide sufficient direction to this "negative proviso" in the specification as filed.

Applicant's arguments, filed 10/26/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

The recitation of HIV is not readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "negative proviso" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.

Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide blaze marks, nor direction for the instant methods encompassing the above-mentioned "negatitve proviso", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "negative proviso" indicated above.
See MPEP 714.02 and 2163.06

Applicant's arguments have not been found persuasive.

6. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated McKenna et al. (US 2004/0022760) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 10/26/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

McKenna et al. teach the use of Flt3-ligand (e.g., see paragraphs [0054] – [0068]) in immunization protocols (e.g., see Therapeutic applications in paragraphs [0089] – [0159]), including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see paragraphs [0078] –[0085], including Table 1 on pages 10-11 and paragraphs [0127] – [0129]) as well as known pharmaceutical compositions (e.g. see paragraphs [0085], [0092], [[0096] - [0120]) and modes of administration (e.g., see paragraphs [0121] –[0126] recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

7. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated Rosenthal et al. (U.S. Patent No. 6,875,441) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 10/26/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Rosenthal et al. teach the use of Flt3-ligand (e.g., see Background of the Invention, column 7, paragraph 3 and Examples) in immunization protocols (e.g., see column 11, paragraph 6) including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see column 11, paragraphs 6-7) as well as known pharmaceutical compositions and modes of administration (e.g., see columns 12-13) recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

8. Claims 1, 3-9, 11-15 and 17-23 are rejected under 35 U.S.C § 102(b) as being anticipated Lyman et al. (U.S. Patent No. 5,554,512) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 10/26/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir. 1997).

Applicant's arguments have not been found persuasive.

In accordance with applicant's arguments, filed 10/26/2007;
Claim 2 has been withdrawn from the rejection of record as it applies to this reference

The following is reiterated for applicant's convenience.

Applicant's arguments, filed 10/26/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Lyman et al. teach the use of Flt3-ligand (e.g., see columns 4-17 and Examples) [0068]) as well as known pharmaceutical compositions and modes of administration (e.g., see column 18, paragraphs 3-4) that can be use in methods to stimulate T cell proliferation as well hemopoietic cells in treating patients with HIV (e.g. see column 7, paragraph 3) encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted that even if applicant is able to obtain the earliest priority document relied upon, this reference would still stand as prior art under 35 USC 102(e).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 22, 2008